

**REMARKS/ARGUMENTS**

The present application has been reviewed in light of the Office Action having a mailing date of October 12, 2007. Claims 1, 6, 7, 16, and 22 are amended. Claims 29-45 are new. Claims 4 and 10-15 are canceled. Accordingly, Claims 1-3, 5-9 and 16-45 are pending.

The Examiner has rejected Claims 1-9 and 16-28 under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 5,735,851 to Errico et al. ("Errico"). Additionally, Claims 3, 19 and 25 stand rejected under 35 U.S.C. §103(a) as being non-obvious in view of Errico. As argued herein, reconsideration and withdrawal of the claim rejections is respectfully requested.

**Summary of the Claimed Invention**

The present invention is generally directed to an implant assembly having an inventive attachment device, a tension link, an implant component and a connector. In accordance with embodiments of the claimed invention, a single securing means operates to both secure the implant component to the connector and secure the connector to the attachment device. In securing the connector to the attachment device, the tension link is connected to the attachment device and received through the tension link cavity associated with the connector. With the connector and the attachment device interconnected through the tension link, the securing mechanism, which is associated with the distal end of the tension link operates to secure these components in place. Additionally, the securing mechanism may operate to secure the implant component to the connector. In that regard, the connector includes an implant component aperture provided in association with a gap. The implant component aperture is operable to receive the implant component and tighten around the implant component when the gap is closed. The gap is closed by a deformation of the connector that occurs as the connector is secured to the attachment device by the securing mechanism. Accordingly, the same action that secures the connector to the attachment device also secures the implant component to the connector.

Embodiments of the claimed invention are directed to an inventive attachment device including a shank having a first end and a second end. The first end includes a securement mechanism, such as a threaded screw. The second end is adapted to receive a head of a tension link. The head is inserted into an aperture and received in a hollow cavity that is defined by a wall. The second end includes a wall having a curved exterior surface and is deformable to allow the head of the tension link to be inserted into the hollow cavity. The tension link is retained within the second end by contact maintained against the curved exterior surface of the second end, which thereby limits the deformation of the second end. In that regard, the attachment device may be provided in association with a connector having a head receptacle. The head receptacle includes a curved surface that engages the curved exterior surface of the second end of the attachment device when the connector is seated on the attachment device. The engagement between the curved surface of the head receptacle and the curved exterior surface of the second end is maintained by a tensile force applied through the tension link. Here, it is also noted that the engagement between the two curved surfaces, and thus the retention of the tension link within the second end of the attachment device, is maintained by the securing mechanism. Accordingly, the securing mechanism serves a third purpose in addition to securing the connector to the attaching device and securing the implant component to the connector. Additionally, it is noted that no screw-type connection exists between the attachment device and the connector. Accordingly, the second end of the attachment device is devoid of threads.

#### **The Implant Assembly - Independent Claims 16 and 32**

Independent Claim 16 has been amended to recite that the tension link is retained within the second end of the attachment device by the engagement between the curved surface of the connector and the curved exterior surface of the attachment device. Accordingly, independent Claim 16, as amended, recites an implant assembly that includes a single component that operates to both secure a tension link head within a second end of an attachment device and to secure a connector to the attachment device. The Errico reference discloses an attachment device

102, a stem 120 and a rod coupling element 160. A locking nut 170, which is associated with the distal end of the stem 120, operates to *only* secure the rod coupling element 160 to the attachment device 102. In sharp contrast to the claimed invention, the stem 120 is retained within the second end of the attachment device through a separate securing means, namely the cuff 132a,b. The Applicant respectfully submits that the reference cited by the Examiner does not disclose or suggest an implant assembly having single securing mechanism that operates both secure a tension link head and to secure a connector to an attachment device, as set forth in Claim 16, as amended. For at least this reason it is respectfully submitted that independent Claim 16 and Claims 17-21 and 31, which depend from Claim 16, are allowable over the prior art.

New Claims 32 is directed to an implant assembly having a single securing means that operates to both secure the implant component to and secure the connector to the attachment device. The Applicant respectfully submits that the reference cited by the Examiner does not disclose or suggest an implant assembly having single securing mechanism that operates to secure both a connector to an attachment device and an implant component to the connector, as set forth in new Claim 32. In particular, the Errico reference discloses an attachment device 102, a stem 120, a rod 200, and a rod coupling element 160. As mentioned above, a locking nut 170, which is associated with the distal end of the stem 120, operates to *only* secure the rod coupling element 160 to the attachment device 102. The rod 200 is secured to the rod coupling element 160 through a separate securing means, namely the set screw 168. For at least this reason it is respectfully submitted that independent Claim 32 and Claims 33-40, which depend from Claim 32, are allowable over the prior art.

It is additionally noted that embodiments of the present invention, as set forth in at least independent Claims 16 and 32, provide an implant assembly that includes a significantly reduced number of discrete parts or components in comparison with Errico and other prior art references of record. The device disclosed by Errico, in particular, requires a cuff 130, a spacer 150 and set screw 168, none of which are needed in the claimed invention. The curved surfaced surfaces associated with the attachment device and the connector, which are recited at least in Claim 16,

obviate the need for the cuff 130 and spacer 150 of Errico. The gap associated with the connector, which is recited in Claim 32, obviates the need for the set screw 168 of Errico. As can be appreciated, having a reduced number of parts greatly reduces the difficulty of manipulating and implanting the device. For at least this additional reason it is respectfully submitted that Claim 16 and Claims 17-21 and 31, which depend from Claim 16; and independent Claim 32 and Claims 33-40, which depend from Claim 32, are allowable over the prior art.

Moreover, a number dependent claims, which depend from Claims 16 and 32 recite additional patentable subject matter. New Claim 31 (which depends from Claim 16) recites a connector having a gap, which when closed by the securing mechanism, operates to secure an implant component in an implant component aperture. Accordingly, the securing mechanism serves a third purpose in addition to retaining tension link in the second end of the attachment device and securing the connector to the attachment device. Similarly, Claim 34 recites a securing mechanism that servers three purposes. In particular, in new Claim 34 (which depends from Claim 32), engagement between the two curved surfaces, and thus the retention of the tension link within the second end of the attachment device, is maintained by the securing mechanism. Accordingly, the securing mechanism serves a third purpose in addition to securing the connector to the attachment device and securing the implant component to the connector. New Claim 37 (which depends from Claim 32) recites an alternative attachment device having an entry channel operable to receive the tension link. New Claim 38 (which depends from Claim 37) recites an alternative attachment device having an tension link slot. The cited references do not teach, suggest or describe these claim elements. Accordingly, for at least this additional reasons, Claims 31, 34, 37 and 38 should be allowed.

#### **The Method of Installing a Surgical Implant Assembly - Independent Claim 8**

For at least the reasons discussed above, it is respectfully submitted that Claim 8 is allowable over the prior art. Claim 8 is directed to a method of installing a surgical implant

assembly. As set forth in Claim 8, the connector is secured to the attachment device and the implant component is secured to the connector by a single action, namely the tightening of the link nut onto the distal end of the tension link. In Errico, as described above, these two attachments are secured by two separate components, namely, the locking nut 170 and the set screw 168. Accordingly, for at least this reason, it is respectfully submitted that Independent Claim 8 and Claims 9 and 30, which depends from Claim 8 are allowable over the prior art.

### **The Attachment Device - Independent Claims 1, 22 and 41**

Independent Claim 1 has been amended to recite that the second end of the attachment device is devoid of threads. Here, is noted that independent Claim 22 also recites this aspect of the present invention. New independent Claim 41 has been added, which recites an attachment device having a second end devoid of threads. Additionally, independent Claims 1 and 22 have been amended to recite an attachment device having a curved exterior surface.

The Applicant respectfully submits that the Examiner has failed to provide a reference that discloses an attachment device having a second end devoid of threads, as set forth in amended Claim 1, Claim 22 and new Claim 41. The Errico reference discloses an attachment device 102 adapted for use with a stem 120, which is retained within the second end of the attachment device 102 through a conventional screw connection. In particular, the Errico device includes a cuff 130, which fits around the stem 120 and attaches to the second end of the attachment device 102, to thereby secure the tension link. In that regard, the cylindrical shaped wall of the second end includes screw threads adapted for engagement with screw threads associated with the cuff 130. In sharp contrast, the second end of the claimed attachment device retains a tension link through the engagement of curved surfaces associated with the attachment device and a head receptacle. Accordingly, the second end of the claimed attachment device is devoid of threads. For at least these reasons, reconsideration and withdrawal of the rejections of independent Claim 1 (and Claims 2-7 and 29 which depend from Claim1), independent Claim 22

(and Claims 23-28 and 31, which depend from Claim 22) and independent Claim 41 (and Claims 42-45, which depend from Claim 41) are respectfully requested.

Here, it is noted that New Claim 41 includes the subject matter of cancelled Claims 10 and 14, which were previously cancelled only to expedite allowance of the present application. In a previous Office Action, Claims 10 and 14 were rejected as being anticipated by United States Patent No. 6,074,393 to Sitoto ("Sitoto"). If a similar rejection is to be applied to new Claim 41, it is respectfully noted to the Examiner's attention that the attachment device disclosed by Sitoto includes a second end having threads. In particular, as can be seen in Fig. 1 of Sitoto and as described in at col. 2 lns. 32-43 of Sitoto, the enlarged head 13 of the screw 10 includes a screw thread hole 18 provided in association with a screw hole 18. Accordingly, as new claim 41 recites a second end devoid of threads, it is respectfully submitted that Claim 41 is allowable over Sitoto.

Moreover, a number dependent claims, which depend from Claims 1, 22 and 41 recite additional patentable subject matter. For example, amended Claim 7 (which depends from independent Claim 1) recites a connector having a head receptacle that operates to secure tension link to the attachment device. This aspect of the claimed invention is discussed above in connection with Claim 16. New Claim 29 (which depends from Claim 7) recites a connector having a gap that, when closed, operates to secure an implant component within an implant component aperture. This aspect of the claimed invention is discussed above in connection with Claim 32.

#### **Rejections of Claims 1-9 and 16-28 under 102(e)**

To constitute anticipation, all material elements of the claim must be found in one prior art source. *In re Marshall*, 198 USPQ 344 (CCPA 1978); *In re Kalm*, 154 USPQ 10 (CCPA 1967). Additionally, the elements of the reference must be arranged as required by the claim. *In re Bond*, 15 USPQ 2d 1566 (Fed. Cir. 1990). Here, Errico et al fails to disclose each and every element of the claimed invention, as explained in detail above. Applicant respectfully submits

that the cited references do not disclose or teach all of the material elements and do not arrange the elements as required by the rejected claim language. Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. §102(e) are respectfully requested.

**Rejections of Claims 3, 19 and 25 under 103(a)**

To support a 103(a) rejection, the examiner must demonstrate that a person of ordinary skill in the art would have had reason to attempt to make the claimed device, or carry out the claimed process, and would have had a reasonable expectation of success in doing so. *See Medichem*, 437 F.3d at 1164; *Noelle v. Lederman*, 355 F.3d 1343, 1351B52 (Fed. Cir. 2004); *Brown & Williamson Tobacco Co. v. Philip Morris, Inc.*, 229 F.3d 1120, 1121 (Fed. Cir. 2000); *see also KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1740 (2007). Ascertaining the differences between the invention, as claimed, and the prior art requires considering both the invention and the prior art as a whole. MPEP §§ 2111 & 2141.02. In determining the differences between the prior art and the claims, the question under 35 U.S.C. §103 is not whether the differences themselves would have been obvious, but whether the claimed inventions as a whole would have been obvious. *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 218 USPQ 871 (Fed. Cir. 1983). Furthermore, an obviousness rejection cannot be based on mere conclusory statements; rather, there must be an articulated reasoning and a rational underpinning to support an obviousness rejection. *KSR*, 82 USPQ2d at 1396. Applicant respectfully submits that the cited references do not disclose or teach all of the material elements and do not arrange the elements as required by the rejected claim language. Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. §103(a) are respectfully requested.

Moreover, Applicant respectfully submits that the attempted combination of Errico et al and Sitoto is not based on the prior art, but instead, must have been based solely on facts within the personal knowledge of the examiner. The examiner admits that Errico et al does not teach at least two expansion slots that are diametrically opposed. The Examiner relies upon a slot of Sitoto and then opines that making slots diametrically opposed would be obvious to one of skill

in the art (which the Examiner has not professed to be) for a reason that is not present in the prior art: "mere duplication of the essential working parts of a device." The Examiner cites to a 30 year old 7<sup>th</sup> Cir. case for a legal proposition that cannot be found in the cited case. For this reason alone, the next office action in this case cannot be made final.

In the event the Examiner persists in such §103 rejection, Applicant respectfully requests that the Examiner provide an affidavit in accordance with 37 CFR §1.104(d)(2). Such section requires that when a rejection in an application is based upon facts within the personal knowledge of the Examiner, the data relied upon should be as specific as possible, and the reference must be supported, when called for by the applicant, by the affidavit of the Examiner, such affidavit to be subject to contradiction or explanation by affidavits of the applicant or other persons. As such, Applicant also respectfully requests the opportunity to respond to any such affidavit of the Examiner if one is submitted.

Based upon the foregoing, Applicants believe that all pending claims are in condition for allowance and such disposition is respectfully requested. In the event that a telephone conversation would further prosecution and/or expedite allowance, the Examiner is invited to contact the undersigned.

Respectfully submitted,  
SHERIDAN ROSS P.C.

By: 

Brian J. Ignat  
Registration No. 57,174  
1560 Broadway, Suite 1200  
Denver, Colorado 80202-5141  
(303) 863-9700

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